The Commonwealth of Massachusetts
Bureau of Health Professions Licensure
Board of Registration in Pharmacy
250 Washington Street, Boston, MA 02108-4619
pharmacy.admin@mass.gov
(617) 973-0960

Application for Pharmacy Modifications Including Remodeling, Change in Configuration, or Change in Square Footage

Pharmacy Name _____MA License Number_____
Pharmacy Address _____
City/Town _____State_____ Zip Code _____
Pharmacy Tel. No. _____Pharmacy Fax No._____
Pharmacy E-mail _____
Name of Manager of Record (MOR) (print)_____
MOR MA License Number_____
MOR Email_____

***Please contact the Board with any questions.**

This application is required for pharmacy modifications involving:

1. remodeling or change in the configuration or square footage of any licensed pharmacy areas (includes the addition of any access points such as a door);
2. addition of contiguous or non-contiguous pharmacy areas (e.g., immunization room, Automated Pharmacy System, counseling room, etc.); and
3. moving, removing, adding, modifying, or replacing of any secondary engineering control in a compounding pharmacy.

This application is not needed for work, repairs, and/or service if:

1. done in response to an urgently needed repair or service (e.g., damage from a broken pipe, storm-related repairs, HVAC system malfunction, etc.) and the Board is notified by email as soon as possible;
2. done in response to a deficiency cited during an inspection and has been detailed in a submitted plan of correction;
3. the work, repairs, and/or service do not require an application as outlined in the section above; and
4. all related documentation is maintained in the pharmacy's records and available for Board inspection.

What are the projected start and completion dates?

If renovating/expanding within in any healthcare facility, documentation of approval from the facility's licensing body(s) must be attached.

Describe all proposed changes including any square footage changes.
Attach additional sheets as needed and applicable documents as below.

☐ **Retail Pharmacies (Drug Stores) must submit:**
- □ Blueprints or architectural drawing (*see page 4 for details*).
- □ Containment strategy / risk mitigation plan.
- □ A written plan to maintain security of controlled substances.

☐ **Sterile Compounding Pharmacies must submit:**
- □ Certified blueprints (*see page 4 for details*).
- □ Sterile Compounding Pharmacy Compliance checklist (*pages 5 - 7*).
- □ Containment strategy / risk mitigation plan.
- □ Environmental monitoring plan.
- □ Plan to recertify primary and secondary engineering controls.
- □ Continuity of care plan.

☐ **Complex Non-Sterile Compounding Pharmacies must submit:**
- □ Certified blueprints (*see page 4 for details*).
- □ Containment strategy / risk mitigation plan.
- □ Plan to recertify any containment hoods.
- □ Continuity of care plan.

☐ **Nuclear Pharmacies must submit:**
- □ Certified blueprints (*see page 4 for applicable details*).
- □ Sterile Compounding Pharmacy Compliance checklist (*pages 5 - 7*).
- □ Containment strategy / risk mitigation plan.
- □ Environmental monitoring plan for sterile compounding areas.
- □ Plan to recertify any primary and secondary engineering controls including any containment hood(s).
- □ Continuity of care plan.

<u>As the MOR, I understand and attest that</u>:

1. The work cannot begin until approved by the Board of Registration in Pharmacy.
2. Any changes to the approved application require approval by the Board of Registration in Pharmacy.
3. It is my responsibility to assure that adequate measures are in place to maintain the security of all controlled substances at all times during the work.
4. It is my responsibility to comply with all state / local building codes as they relate to this pharmacy.
5. It is my responsibility to assure that primary and secondary engineering controls are properly tested and recertified prior to reengaging in compounding activities, as applicable.
6. I will notify the Board when the work will be completed or if it will not be completed within the estimated timeline.
7. All related documentation will be maintained in the pharmacy's records and available for Board inspection.

MOR Name (print): _____

MOR Signature: _____ Date: _____

_____

Board Staff Signature Date approved

Requirements for Certified Blueprints/Architectural Drawings

Drug Store Pharmacy	A **blueprint/architectural drawing**** with the current layout outlined in **BLUE** and proposed pharmacy layout outlined in **RED**, drawn to scale with the following items clearly labeled: 1. square footage* 2. prescription area 3. a legend explaining all abbreviations 4. patient consultation area 5. Automated Pharmacy System ("APS") location, if applicable; 6. drop off and pickup windows 7. pick-up bins 8. refrigerator 9. safe 10. sink 11. designated non-sterile compounding area (draft 247 CMR 18.00 will require 10 square feet of counter space for non-sterile compounding) 12. other pertinent details ***** DO NOT include areas such as consultation rooms, front store area, offices, or restrooms in the proposed licensed square footage total.
Complex Non-Sterile Compounding Pharmacy	A **certified blueprint**** with the current layout outlined in **BLUE** and proposed pharmacy layout outlined in **RED**, drawn to scale with the following items clearly labeled: 1. all requirements listed above for Drug Store Pharmacy 2. designated non-sterile compounding area, if applicable 3. the dedicated compounding room, including placement of containment hood(s) 4. detailed HVAC design plan and written description 5. room pressurization, if applicable 6. hazardous drug storage area, if applicable 7. other pertinent details.
Sterile Compounding Pharmacy	A **certified blueprint**** with the current layout outlined in **BLUE** and proposed pharmacy layout outlined in **RED**, drawn to scale with the following items clearly labeled: 1. all requirements listed above for Drug Store Pharmacy 2. designated non-sterile compounding area, if applicable 3. proposed pharmacy layout outlined in red, include square footage of each room 4. location and ISO classification of each primary and secondary engineering control 5. air flow 6. room pressurization 7. detailed HVAC design plan and written description 8. location of any pass-throughs 9. hazardous drug storage area, if applicable 10. other pertinent details.

**** All blueprints/architectural drawings must be submitted electronically.**
A certified blueprint must be stamped with an architect's seal along with the architect's signature.

Sterile Compounding Pharmacy Compliance

If the proposed design meets the listed requirement, please indicate by placing "Y" (yes) or "N" (no) and include comments as to the reason for the non-compliance and plans to mitigate. If not applicable, indicate with "NA".

Please note that this is not an all-inclusive list of proposed standards in Draft 247 CMR 17.00 or the requirements of USP. At a minimum, applicants are required to adhere to the standards set forth in the most recent version of USP <797> and USP <800>. It is the responsibility of the applicant to be familiar with the requirements set forth in USP chapters and the Board's regulations.

Draft 247 CMR 17.00	Citation	Y/N	Comments
Miscellaneous:			
A pharmacy may not compound non-sterile preparations in any Primary Engineering Control (PEC) or Secondary Engineering Control (SEC) used for sterile compounding.	17.03(8)		
A pharmacy shall have a dedicated changing area for sterile compounding personnel.	17.04(2)		
Primary Engineering Controls (PECs):			
A pharmacy shall utilize only commercially manufactured PECs.	17.06(1)		
All Secondary Engineering Controls (SECs):			
The doors leading into and between ISO Classified SECs shall be constructed with an interlocking design or utilize an alternative method to ensure that doors are not opened simultaneously.	17.07(1)(c)		
Unless prohibited by local building or fire code, an SEC may not have more than one door to immediately adjacent areas.	17.07(1)(b)		
Each newly constructed SEC shall allow for visual observation through windows or technology.	17.07(1)(a)		
SECs may not contain windows to the outdoors.	17.07(1)(k)		
A pharmacy shall ensure that any pass-through chambers: a. have an interlocking door design; and b. are not refrigerator units.	17.04(1)		
Walls shall be made of solid surface materials such as locking sealed panels or epoxy-coated gypsum board.	17.07(1)(j)		
Ceiling panels, fixtures, and other penetrations through the ceiling or walls shall be smooth and sealed around the perimeter.	17.07(1)(h)		
SECs shall utilize light fixtures designed for sterile compounding areas (i.e., cleanroom grade) that have an exterior surface that is smooth, mounted flush with the ceiling, and sealed.	17.07(1)(g)		

Sprinkler heads shall be recessed, covered, and easily cleanable.	17.07(1)(i)		
Floors shall be composed of wide sheet vinyl that is heat sealed at the seams, or other solid, smooth surface, and coved at the wall or appropriately sealed.	17.07(1)(l)		
SECs may not contain floor drains.	17.07(1)(f)		
A pharmacy may not locate a refrigerator in any ISO Classified SEC.	17.07(1)(e)		
A pharmacy may not use ISO Classified areas for drug storage.	17.04(3)		
Ante Rooms:			
A newly constructed ante room shall be at least 72 square feet.	17.07(3)(a)		
For hand hygiene, an anteroom shall have a stainless-steel sink that is located on the clean side of the line of demarcation at least one meter away from the buffer room door.	17.07(3)(b)		
The stainless-steel sink shall: i. be equipped with hands-free controls for water and soap dispensing; ii. have proper depth and capacity for hand washing up to the elbows; iii. minimize splashing and dripping of water; iv. be designed to prevent standing water; and v. have a faucet that does not have an aerator mechanism on the nozzle.	17.07(3)(c)		
An ante room shall have low-lint, disposable towels located in close proximity to the sink.	17.07(3)(d)		
Buffer Rooms:			
A newly constructed **non-hazardous drug** buffer room shall be at least 100 square feet.	17.07(2)(a)		
A newly constructed **hazardous drug** buffer room shall be at least 72 square feet.	17.07(2)(b)		
Buffer room doors shall be hands-free.	17.07(2)(c)		
HVAC			
Newly constructed ISO Classified SECs shall utilize a closed loop ducted system, a sealed plenum system, or equivalent HVAC design.	17.05(1)		
Supply air provided for each ISO Classified SEC shall be provided exclusively through ceiling mounted HEPA filters.	17.05(3)		
Air returns in ISO Classified SECs shall be mounted low on the walls	17.05(4)		
If utilized, relief air vents shall be mounted low on the wall and designed to prevent the ingress of less clean air or contaminants from adjacent areas.	17.05(5)		
Temperature/Humidity			
A pharmacy shall have a system to continuously measure the temperature and humidity of each	17.10(3)		

SEC. The quantitative results shall be reviewed and documented at least daily on all days the pharmacy is open.			
SECs shall maintain a temperature of 68 degrees Fahrenheit (20 degrees Celsius) or lower.	17.10(1)		
SECs shall maintain relative humidity of 60% or lower.	17.10(2)		